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RD

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/379,270	08/23/99	DE LEYS	R BARP025--2/K

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HM12/0602

EXAMINER

ZEMAN, R

ART UNIT	PAPER NUMBER
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1645

DATE MAILED:

4
06/02/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/379,270

Applicant(s)

De Leys, et al.

Examiner

Robert A. Zeman

Group Art Unit

1645



☒ Responsive to communication(s) filed on Aug 23, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 37 and 38 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 37 and 38 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☒ received in Application No. (Series Code/Serial Number) 08/900,902.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Priority

Applicant's claim that the instant application is a continuation of application Serial No. 08/900,902, filed on July 25, 1997, now issued as U.S. Patent 6,013,484, which is a divisional of application Serial No.08/486,836 filed on June 7, 1995, now issued as U.S. Patent No. 5,795,743, which is a divisional of application Serial No.08/228,519 filed on April 15, 1994, now issued as U.S. Patent No. 5,567,603, which is a divisional of application Serial No.07/460,913 filed on March 23, 1990, now issued as U.S. Patent No. 5,304,466, which claims benefit under 35 U.S.C 120 of PCT/EP89/00643, filed on June 8, 1989 and claims priority under 35 U.S.C. 119 of EP 88 109 200.1, filed June 9, 1988, is acknowledged.

Amendment

The cancellation of claims 1-36 and the addition of claims 37-38 in Paper No. 3 is acknowledged. Claims 37 and 38 are pending and currently under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37 and 38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the variant of HIV-3 retrovirus is required in order to practice the claimed invention. Specifically, it is noted that claim 12 recites deposited material in the body of the claim. The deposit of biological organisms is considered by the Examiner to be necessary for enablement of the current invention {see 37 CFR 1.808(a)}.

If a deposit is made under terms of the Budapest Treaty, then an affidavit or declaration by Applicants or person(s) associated with the patent owner (assignee) who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty *and* that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, than an affidavit or declaration by Applicants or person(s) associated with the patent owner (assignee) who is in a

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position to make such assurances, or a statement by an attorney of record over his or her signature, should be submitted stating that the deposit has been made at an acceptable depository *and that* the following criteria have been met:

- 1) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;
- 2) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;
- 3) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;
- 4) a viability statement in accordance with the provisions of 37 CFR 1.807; and
- 5) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 37 and 38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5, 6 and 14 of U.S. Patent No. 5,567,603. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are drawn to a HIV-3 variant with the same component proteins and biochemical properties.

For the purposes of this examination, proteins with molecular weights of "about" 12 kD, 17 kD, 25 kD, 31 kD, 49 kD, 62 kD, 41 kD and 120 kD are interpreted to be those proteins depicted in Figures 5 and 6. "Stringent conditions" are interpreted to be those described in Example 3A.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 38 is rendered vague and indefinite by the use of the phrase "its LTR sequence is **about 70% or less** homologous to the LTR sequence of HIV-1 or HIV-2". What HIV-1 or HIV-2 LTR sequence is Applicant using as his reference point? As written it is impossible to determine the metes and bounds of the claimed invention.

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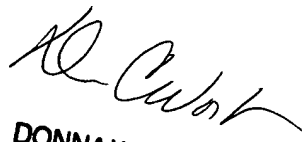
Conclusion

No claim is allowed.

Claims 37 and 38 are free of the art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Anthony Caputa, can be reached at (703)308-3995.


DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman

May 31, 2000